

## Food and Drug Administration, HHS

## § 880.6300

to prevent contamination between patient and examiner.

(b) *Classification*. Class I (general controls).

[45 FR 69682, Oct. 21, 1980, as amended at 54 FR 1604, Jan. 13, 1989; 66 FR 46952, Sept. 10, 2001]

### § 880.6260 Filtering facepiece respirator for use by the general public in public health medical emergencies.

(a) *Identification*. A filtering facepiece respirator for use by the general public in public health medical emergencies is a device that is a disposable half-facepiece non-powered air-purifying particulate respirator intended for use to cover the nose and mouth of the wearer to help reduce wearer exposure to pathogenic biological airborne particulates during a public health medical emergency. The device is made of polymeric materials and is intended to fit closely to the face and to function by filtering particulate material.

(b) *Classification*. Class II (special controls). The special controls are:

(1) Certification by the National Institute for Occupational Safety and Health (NIOSH) as a non-powered air-purifying particulate respirator with a minimum filtration efficiency classification of N95, in accordance with 42 CFR part 84.

(2) The FDA guidance document entitled: "Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Filtering Facepiece Respirator for use by the General Public in Public Health Medical Emergencies." See § 880.1(e) for information on obtaining a copy of this guidance document.

[72 FR 36362, July 3, 2007]

### § 880.6265 Examination gown.

(a) *Identification*. An examination gown is a device intended for medical purposes that is made of cloth, paper, or other material that is draped over or worn by a patient as a body covering during a medical examination.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. If the device is not labeled or otherwise

represented as sterile, it is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[45 FR 69682, Oct. 21, 1980, as amended at 66 FR 38806, July 25, 2001]

### § 880.6280 Medical insole.

(a) *Identification*. A medical insole is a device intended for medical purposes that is placed inside a shoe to relieve the symptoms of athlete's foot infection by absorbing moisture.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9.

[45 FR 69682, Oct. 21, 1980, as amended at 54 FR 25050, June 12, 1989; 66 FR 38806, July 25, 2001]

### § 880.6300 Implantable radiofrequency transponder system for patient identification and health information.

(a) *Identification*. An implantable radiofrequency transponder system for patient identification and health information is a device intended to enable access to secure patient identification and corresponding health information. This system may include a passive implanted transponder, inserter, and scanner. The implanted transponder is used only to store a unique electronic identification code that is read by the scanner. The identification code is used to access patient identity and corresponding health information stored in a database.

(b) *Classification*. Class II (special controls). The special control is FDA's guidance document entitled "Class II Special Controls Guidance Document: Implantable Radiofrequency Transponder System for Patient Identification and Health Information." See § 880.1(e) for the availability of this guidance document. This device is exempt from the premarket notification procedures in subpart E of part 807 of

## § 880.6305

this chapter subject to the limitations in § 880.9.

[69 FR 71704, Dec. 10, 2004]

### § 880.6305 Ingestible event marker.

(a) *Identification.* An ingestible event marker is a prescription device used to record time-stamped, patient-logged events. The ingestible component links wirelessly through intrabody communication to an external recorder which records the date and time of ingestion as well as the unique serial number of the ingestible device.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The device must be demonstrated to be biocompatible and non-toxic;

(2) Nonclinical, animal, and clinical testing must provide a reasonable assurance of safety and effectiveness, including device performance, durability, compatibility, usability (human factors testing), event recording, and proper excretion of the device;

(3) Appropriate analysis and nonclinical testing must validate electromagnetic compatibility performance, wireless performance, and electrical safety; and

(4) Labeling must include a detailed summary of the nonclinical and clinical testing pertinent to use of the device and the maximum number of daily device ingestions.

[78 FR 28734, May 16, 2013]

### § 880.6310 Medical device data system.

(a) *Identification.* (1) A medical device data system (MDDS) is a device that is intended to provide one or more of the following uses, without controlling or altering the functions or parameters of any connected medical devices:

(i) The electronic transfer of medical device data;

(ii) The electronic storage of medical device data;

(iii) The electronic conversion of medical device data from one format to another format in accordance with a preset specification; or

(iv) The electronic display of medical device data.

(2) An MDDS may include software, electronic or electrical hardware such as a physical communications medium

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(including wireless hardware), modems, interfaces, and a communications protocol. This identification does not include devices intended to be used in connection with active patient monitoring.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9.

[76 FR 8649, Feb. 15, 2011]

### § 880.6315 Remote Medication Management System.

(a) *Identification.* A remote medication management system is a device composed of clinical and communications software, a medication delivery unit, and medication packaging. The system is intended to store the patient's prescribed medications in a delivery unit, to permit a health care professional to remotely schedule the patient's prescribed medications, to notify the patient when the prescribed medications are due to be taken, to release the prescribed medications to a tray of the delivery unit accessible to the patient on the patient's command, and to record a history of the event for the health care professional. The system is intended for use as an aid to health care professionals in managing therapeutic regimens for patients in the home or clinic.

(b) *Classification.* Class II (special controls). The special control is: The FDA guidance document entitled "Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Remote Medication Management System." See § 880.1(e) for availability of this guidance document.

[72 FR 59177, Oct. 19, 2007]

### § 880.6320 AC-powered medical examination light.

(a) *Identification.* An AC-powered medical examination light is an AC-powered device intended for medical purposes that is used to illuminate body surfaces and cavities during a medical examination.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in